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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,861	02/15/2005	Bernard Bouffier	BDL-67	3004
20311	7590	06/30/2006		
LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK, NY 10016			EXAMINER HOPKINS, CHRISTINE D	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/524,861

Applicant(s)

BOUFFIER, BERNARD

Examiner

Christine D. Hopkins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-36 and 38-40 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>15 February 2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show element 100 (the introducer device) of Fig. 3 and element 113a of Fig. 2 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Furthermore, the drawings are objected to because line 6 of pg. 16 recites “the arms” as element 58 and should apparently read—(48)--. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 17-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Skiba et al. (U.S. Patent No. 6,908,473). Skiba et al. (hereinafter Skiba) disclose an invention comprising a tissue anchoring device and suspending device used in conjunction with the tissue anchoring device for engaging and supporting an organ. In reference to claims 17 and 34, the invention of Skiba comprises “an elongated component” or suspending device (element 50 of Fig. 5a) that acts as a sling and is flexible so that it may engage a biological vessel or organ (col. 9, lines 25-29). Skiba also teaches an anchoring device comprising a “traction component” (element 24) and connector (element 14 of Fig. 4a), or “sliding component” that work in conjunction to facilitate elastic compliance from a pulling force placed on the bladder by the sling, or “elongated support component”. Furthermore, the anchoring device of Skiba assumes the form of a “cage” as presented in Fig. 2b, and is configured to enable pulling on the proximal portion (element 24), or “traction component” for suspending the bladder in the proper position as a result of it’s direct force on the sling or “elongated support component” (col. 8, lines 1-31). With respect to claim 18, the anchoring device of Skiba may be

inserted into a tissue or biological vessel of interest, such as a urethra (col. 10, lines 25-32).

In reference to claim 19, the anchoring device of Skiba is constructed from a biocompatible polymer, or "flexible and deformable material" (col. 7, lines 15-19) and comprises "lateral arms" (element 16) as portrayed in Fig. 2b. Furthermore, in view of claim 20, the "lateral bridging arms" of Skida may form a "kink" (as depicted in the transition from Fig. 2a to 2b) after insertion into the tissue region (element 20).

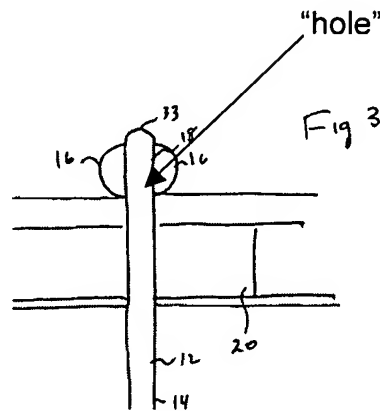
With respect to claim 21, the connector or "sliding component" (element 14) of the anchoring device of Skiba is configured to be subject to considerable pulling forces resulting from the draw on the bladder by the "elongated support component" or suspending device, element 50 (col. 8, lines 1-13).

With respect to claim 22, the "traction component," or proximal portion (element 24) of the connector (element 14), comprises holes or loops which facilitate connection to, and pulling on the "elongated sling," or suspending device in the invention of Skiba (col. 8, lines 1-8). In reference to claim 23, one anchoring device (element 10) may be employed for supporting both ends of the suspending device as portrayed in Fig. 8 of Skiba. Furthermore, in view of claim 24, the invention of Skiba may additionally include two anchoring devices as presented in Fig. 6.

The anchoring device of Skiba forms a "cage" and contains at its upper end a "tubular component" (element 18 of Fig. 2b) and forms a region for the "sliding component," or connector, which is configured with holes for pulling the traction component (col. 8, lines 1-8). Furthermore, with respect to claim 26, the opposing end

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of element 33 comprises a "hole" which rests against the tissue of the patient as depicted in Fig. 1 of the instant application.



In view of claims 27 and 28, the lower part of the anchoring device of Skiba (element 32) contains a hole through which a syringe or needle may be passed (col. 7, lines 45-49).

With respect to claims 29-30, the suspending device (element 50), or "elongated support component" of Skiba must engage a biological vessel or urethra necessitating its construction from a flexible strip of material such as the patient's abdominal fascia, a fibrous tissue (col. 9, lines 25-29 and col. 2, lines 36-40). Furthermore, in reference to claims 31-32, the invention of Skiba also may be fabricated from a high molecular weight polyethylene (col. 8, lines 33-38). Moreover, the "traction component" or proximal portion of the connector of Skiba may be constructed from the same material, as stated above for providing support to the suspending device or "elongated sling" (col. 8, lines 1-8 and 33-44).

In view of claim 35, the invention of Skiba incorporates an “introducer instrument” or syringe (element 136) and a “protective sheath” or a “guide” (element 128) for fixating the anchoring device (col. 12, lines 21-32). Also refer to Figs. 7-8.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over LoVuolo (U.S. Pub. No. 2002/0143234) in view of Kovac (U.S. Patent No. 6,599,235). LuVuolo discloses a method and apparatus for suspending and stabilizing a bodily structure, also comprising a device for delivering the suspension apparatus. In view of claim 36, LoVuolo discloses local anesthesia in an incontinence procedure [0008]; performing an incision on either side of the urethra [0062]; inserting a “support component” [0070] and subsequently a “trocar instrument” with a “protective sheath” or cannula, element 18 [0063], further containing an “anchoring system” or anchoring toggle (element 32) which cooperates with a “traction component” or suture, element 34 or 36 [0061], and inserted through the incision [0063] and eventually withdrawn from the patient's body [0065]. The ends of the sutures, or “traction component” will be pulled in an effort to sustain the system of LuVuolo [0067]. Furthermore, these steps may be repeated through a second incision [0063]. The end of the “traction component” or suture may be received

by the receiving tubes (element 50 and 52), or end of the sling, to be joined together and the sutures further tied in a knot or "loop" for supporting the sling and cradling the urethra [0066], [0067] and [0069]. However, LuVuolo does not teach a method of closure for the incision. Kovac discloses an invention and method for treating urinary incontinence by way of urethra stabilization. The method of Kovac teaches repair by suturing, or "closure of the incision with a suitable means" (col. 8, lines 15-18).

Therefore, at the time of the invention it would have been obvious for one of ordinary skill in the art to have made the method of LuVuolo to include the suturing of Kovac in an effort to close or repair an area of dissection or incision.

6. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over LuVuolo (U.S. Pub. No. 2002/0143234). In reference to claims 38-40, the method and invention of LoVuolo applies to the compression or stabilization of the female urethra [0001], where the anchoring device of the invention is inserted on tissue of the wall of the pelvic cavity (refer to Fig. 4).

Allowable Subject Matter


7. Claim 37 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach a method wherein a "cage-forming device" constructed of "a series of lateral bridging arms" will induce a "kink" at their mid-point for anchoring, or fixating the device to a surface.

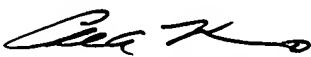
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Christine D Hopkins
Examiner
Art Unit 3735


Charles A Marmor, II
SPE, Art Unit 3735